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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,676	09/27/2001	Yem Chin	BSX-219	8991
7590 02/06/2006			EXAMINER	
FULBRIGHT & JAWORSKI L.L.P. 801 Pennsylvania Avenue, N.W. Washington, DC 20004-2615			EREZO, DARWIN P	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 02/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/963,676

Applicant(s)

CHIN ET AL.

Examiner

Darwin P. Erezzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10, 11, 21-23, 25-29, 31, 32 and 34-39 is/are pending in the application.
- 4a) Of the above claim(s) 10, 11, 21-23, 25, 26 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-29, 31, 32 and 35-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 27, 28, 31, 35-37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,425,376 to Banys et al. and in view of US 6,574,497 to Pacetti.

Banys teaches a method for determining a length of exposure of a tissue cutting device from a catheter/cannula by observing the tissue cutting device which is entirely made of radiopaque (col. 6, line 9), then deploying said cutting device to the tissue. The length of the exposure of the cutting device is related to the distance of which the cannula is withdrawn (col. 6, lines 3-10). Though Banys teaches the cutting device being radiopaque, he fails to teach the radiopaque material arranged as a plurality of radiopaque indicia at measurable intervals. However, as seen in Fig. 3 of Pacetti, it is known in the art to provide a cutting device (needle, see abstract) with a plurality of

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radiopaque indicia at measurable intervals (for example: **60, 62**). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Banys to include a plurality of spaced radiopaque indicia because having said plurality of spaced radiopaque indicia would allow the practitioner to monitor the distal and proximal portion of the biopsy needle, which would provide better positional accuracy than a single radiopaque indicia (the needle). Also, the distal or proximal radiopaque indicia is fully capable of being used as a reference point, as in a leading indicia or trailing indicia. The above combination of Banys/Pacetti also teaches the arrangement of the recited device claims, as the structure is also recited in the method steps. Pacetti also discloses having more than two radiopaque indicia, as seen in Fig. 10.

4. Claims 29, 32 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banys et al. in view Pacetti, and in further view of US 4,588,399 to Nebergall et al.

Banys teaches using a radiopaque biopsy needle to determine the location of a cutting device from a cannula but does not specifically recite the cannula having a radiopaque material. However, it would be obvious to one of ordinary skill in the art to use a cannula having a radiopaque tip, such as the one taught by Nebergall, because in order to determine the location of the cutting device relative to the cannula, it would be necessary to use the cannula as a reference point. Since Banys teaches using fluoroscopy to monitor the needle, it would be obvious to provide a reference point that is also usable under fluoroscopy, such as a cannula with a radiopaque tip.

***Response to Arguments***

5. Applicant's arguments with respect to claims 27-29, 31, 32 and 35-39 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571) 272-4695. The examiner can normally be reached on M-F (7:30-4:00).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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GLENN K. DAWSON  
PRIMARY EXAMINER